HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

m 8124

Food and Drug Administration
Public Health Service

Refer to: CFN 1121996

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4099

April 9, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Daniel Schaub, President
Bay State Medical, Inc.
7466 New Ridge Road, Suite 10R
Hanover, Maryland 21076

Dear Mr. Schaub:

During a Food and Drug Administration (FDA) inspection of your firm located in Hanover, Maryland on March 26 and, 27 and April 1, 1997, our investigators determined that your firm deviated from current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations (CFR), Part 211) during the oxygen manufacturing operation. The deviations observed render your firm's Oxygen, USP products adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (FD&C Act). Those deviations are as follows:

1. Failure to test liquid Oxygen, USP [redacted] to determine conformance with appropriate specifications for identity and purity and to assure the validity of a Certificate of Analysis received from the supplier by testing the identity of the component.

2. Failure to test liquid Oxygen, USP prior to the release for distribution.

3. Failure to properly calibrate the oxygen analyzer on the days that preventive maintenance was performed on the cryogenic home vessels. The firm did not have a reference standard gas cylinder to calibrate the oxygen analyzer or the manufacturer's instruction manual for oxygen analyzer [redacted] prior to and during the inspection. Although these two items were obtained, the individuals have not been trained in the proper calibration of the oxygen analyzer..

4. Failure to assure that employees have been adequately trained to witness the testing of the supplier's analytical methodology, to transfill liquid Oxygen, USP and to practice Good Manufacturing Practices in order to perform the assigned function.

5. Failure to establish written procedures and to maintain a distribution record for [redacted] to facilitate its recall if necessary.

6. Failure to establish written procedures for the cleaning and maintenance of cyrogenic home vessels.

7. Failure to have batch records reviewed by a second individual to determine compliance with all established, approved written procedures before a batch is released or distributed.

Additionally, your liquid oxygen products were determined to be misbranded within the meaning of Section 502(f)(1) of the FD&C Act, in that Oxygen, USP is regarded as a prescription drug, and labeling on the cryogenic home units fails to bear adequate directions for use, in accordance with 21 CFR 210.100(c).

Your liquid oxygen products are further misbranded within the meaning of Section 502 of the FD&C Act, in that the labeling fails to indicate if it has been produced by the air-liquefaction process as required by the United States Pharmacopeia .

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters related to drugs, so that they may take this information into account when considering the award of contracts.

By copy of this letter, we are advising the Health Care Financing Administration that our inspection revealed significant deviations from the FD&C Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems

necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be directed to the Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201, Attention Diane T. O'Brien, Acting Compliance Officer.

Sincerely yours,

Carl E. Draper
Acting Director, Baltimore District